REMARKS

In response to the Office Action mailed October 23, 2007, favorable reconsideration is respectfully requested in view of the above amendments and the following remarks. Claims 19, 61, and 63 are currently under examination. By the above amendment, claim 61 has been amended to recite certain aspects of the invention, without prejudice to prosecution of any subject matter removed or modified by this amendment in a related divisional, continuation or continuation-in-part application.

Rejections Under 35 U.S.C. § 103(a)

Claims 19, 61 and 63 remain rejected under 35 U.S.C. § 103(a) as being obvious over Momin *et al.* (U.S. Patent No. 6,146,632), Billing-Mendel *et al.* (U.S. Patent No. 6,130,043), and Apostolopoulos *et al.* (Vaccine, 14(9):930-938, 1996).

The Examiner maintains the position that it would have been obvious to one of skill in the art to modify the immunogenic composition of Momin *et al.* with the polypeptide of Billing-Mendel *et al.* and administer the immunogenic composition to prostate cancer patients with the purpose of inducing a Th1-type immune response. The Examiner asserts that the motivation to combine Momin *et al.* with Billing-Mendel *et al.* is provided by the teachings of Apostolopoulos *et al.*

Momin *et al.* teaches adjuvant compositions comprising MPL and QS21, and their use for preferential stimulation of IgG2a production and a Th1 cell response. Momin *et al.* also teaches that the adjuvant compositions can be used in conjunction with "*tumour antigens*" where it is desired to stimulate a Th1 immune response.

Billing-Mendel *et al.* teaches a polypeptide of 242 amino acids (SEQ ID NO. 36) expressed in prostate cancer tissue, which shares identity with a portion of the instantly claimed SEQ ID NO. 113. Billing-Mendel *et al.* describes that the polypeptide is a prostate cancer diagnostic marker, and that the polypeptide is used to generate antibodies. Billing Mendel *et al.* does not teach anything related to the T-cell immunogenicity of the described polypeptide or that it could be administered to a cancer patient for therapeutic purposes.

The Examiner acknowledges that Billing-Mendel *et al.* does not teach that the described polypeptide is a T-cell immunogen, but asserts that this deficiency is not important and not relied upon in the outstanding rejection. Yet, at the same time, an apparent basis upon which the Examiner's position is predicated is that the polypeptide of Billing Mendel *et al.* is a "tumor antigen." However, in order for the polypeptide of Billing Mendel *et al.* to be considered a tumor antigen for human T-cells its immunogenicity for human T-cells must have first been established. Absent this, there is no reasonable motivational link to lead a skilled artisan to combine a polypeptide of Billing-Mendel *et al.* with an adjuvant combination of Momin *et al.*

The polypeptide of Billing-Mendel *et al.* is a human polypeptide, *i.e.*, it is a self-protein in humans. The immune system, by design, does not elicit immune responses against its own self-proteins in normal physiological contexts and, in this respect, there is no guarantee that a given human protein will be effective in stimulating a human T-cell response. Thus, the human polypeptide of Billing-Mendel *et al.* would not be considered a tumor antigen, as asserted by the Examiner, when its antigenicity in the context of self was unknown and unpredictable. It does not follow from the fact that Billing-Mendel *et al.* produced antibodies in rabbits that the described polypeptide is a tumor antigen and would be effective in stimulating a human T-cell response. Rather, it is only in light of Applicants' disclosure that a skilled artisan would expect that an effective T-cell immune response could be generated and, as a result, it is only in light of Applicants' disclosure that a skilled artisan would have reason to combine the claimed polypeptides with an immunostimulant that favors a T-cell immune response, as claimed.

The Examiner also asserts that the motivation to combine Momin *et al.* with Billing-Mendel *et al.* is provided by the teachings of Apostolopoulos *et al.* However, Apostolopoulos *et al* describes that, for mucin, it was already known that in the lymph nodes of patients with breast and other cancers cytotoxic lymphocytes are found that react with the protein. Thus, scientific evidence had established that mucin, although a self protein, was capable of stimulating human T-cells and, in this respect, the protein was already known to be a human *tumor antigen* for T-cells. Thus, one skilled in the art may have found motivation to combine the adjuvants of Momin *et al.* with a conjugate mucin polypeptide of Apostolopoulos *et al.* in order to further elicit a cellular-based response because it was already known that mucin

was a human T-cell immunogen and it was further known that a cellular immune response, at least for mucin, was important in a therapeutic context. However, as noted above, the polypeptide of Billing-Mendel *et al.* was not known as a tumor antigen prior to Applicants' disclosure and without this knowledge one skilled in the art would not have been motivated to combine the teachings of Momin *et al.* and Apostolopoulos *et al.* with the polypeptide of Billing-Mendel *et al.*

In addition, Applicants disagree with the Examiner's assertion that Applicants are attempting to claim a latent or inherent property of the prior art. Applicants have discovered certain structural features of SEQ ID NO: 113 that may be associated with a latent property, that is, the presence of a naturally processed human T-cell epitope corresponding to amino acid residues 367-375 of SEQ ID NO: 113. However, the present claims are not directed solely to a polypeptide comprising amino acid residues 367-375 of SEQ ID NO: 113. Applicants' claims are drawn to particular compositions wherein the claimed polypeptide, containing the identified T-cell epitope, is combined with an immunostimulant type that favors a T-cell based immune response. Thus, Applicants are claiming novel combinations that flow from their delineation of the structural features associated with a latent property; they are not claiming the latent property itself. Further, the motivation to select this class of immunostimulants, in combination with the claimed polypeptides comprising amino acid residues 367-375 of SEQ ID NO: 113, can only be obvious to the skilled artisan only following Applicants' identification that the polypeptide is a human T-cell tumor antigen.

Reconsideration of this rejection is respectfully requested.

Rejections Under 35 U.S.C. § 112

Claims 19, 61 and 63 remain rejected under 35 U.S.C. § 112 as allegedly failing to comply with the written description requirement. According to the Examiner, while the claims have been amended to recite fragments of SEQ ID NO: 113 comprising residues 367-375 of SEQ ID NO: 113, the claims encompass an extremely large genus of polypeptides based on the transitional term "comprising."

Without acquiescing to the stated grounds for rejections, and without prejudice to prosecution of this subject matter in a related application, Applicants have amended claim 61 such that the claimed polypeptide is SEQ ID NO: 113 or a fragment of SEQ ID NO: 113 *consisting of* at least amino acid residues 367-375 of SEQ ID NO: 113. Thus, the claimed fragments are defined with particularity as being derived from SEQ ID NO: 113 and minimally containing the identified naturally processed T-cell epitope corresponding to residues 367-375 of SEQ ID NO: 113.

Reconsideration and withdrawal of this rejection is respectfully requested.

The Director is authorized to charge any additional fees due by way of this Amendment, or credit any overpayment, to our Deposit Account No. 19-1090.

Favorable reconsideration is requested.

Respectfully submitted,

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